

**Cooperative Research with NIA  
November 2004**

Investigators Collaborating with the National Institute on Aging Intramural Research Program

- I. **Recitals.** The National Institute on Aging Intramural Research Program (NIA IRP) has a long-standing history of collaborative research with Johns Hopkins University investigators. Until recently, the NIA IRP was located exclusively on the JHBMC campus and JHM IRB 5 reviewed their human subjects research protocols. In April 2003, clinical investigators at the NIA IRP moved to Harbor Hospital and this necessitated a change in the IRB review process. NIA IRP was removed from the Johns Hopkins' Federal Wide Assurances and the MedStar Research Institute (MRI) IRB was designated as the IRB of record for NIA IRP projects. More recently, The Johns Hopkins University entered into an IRB review agreement with MRI. Under expanded terms of that agreement JHM and MRI agree to recognize IRB action of their respective IRB for limited purposes and under certain circumstances. The MRI agreement necessitated a revision in the guidelines for collaborative clinical research involving Johns Hopkins faculty and National Institute on Aging intramural investigators.
  
- II. **All NIA IRP clinical research conducted entirely or primarily at Harbor Hospital, or at other NIA IRP federal or leased facilities, will be reviewed by the MRI IRB.** The Johns Hopkins Institutional officials will be notified in writing of any protocol reviewed by the MRI IRB that includes a principal or associate investigator who is being paid by The Johns Hopkins University ("Hopkins Investigator") along with a copy of the approved protocol. The individuals to be notified are 1) The Director of the Office of Human Subjects Research and 2) The Assistant Dean for Human Subjects Research Compliance. The MRI IRB will have the approval authority and monitoring responsibility for these studies.
  
- III. **All NIA IRP clinical research conducted at other than Johns Hopkins facilities in which the involvement of Hopkins Investigators is limited to review of data, specimens, etc., will be reviewed by the Medstar IRB.** The MRI IRB will have approval authority and monitoring responsibility for these studies. The MRI IRB will provide to Johns Hopkins Institutional officials a copy of the MRI IRB-approved protocol for their information.
  
- IV. **All NIA IRP clinical research conducted in part at Johns Hopkins' facilities and involving an investigational drug or device on which an associate Hopkins Investigator holds the IND, will be reviewed by the JHM IRB for the part of the research involving the investigational drug or device.** JHM IRB review and approval and ongoing monitoring will be required for the part of the project involving the investigational drug or device. The JHM investigator

must submit a separate protocol with a separate informed consent document for JHM review. The MRI IRB will receive a copy of the Johns Hopkins IRB-approved protocol and consent. The individuals who will be notified are the Director, Office of Regulatory Affairs at MRI and Director of Clinical Services at NIA.

- V. **All NIA IRP clinical research conducted in its entirety at Johns Hopkins facilities in which the NIA IRP staff are principal or associate investigators, will be reviewed by the JHM IRB.** The review outcome, including consent documents, will be provided to the MRI IRB for their information.
- VI. **Record Retention and Production.** Consent and HIPAA issues are addressed in the Memorandum of Understanding between Johns Hopkins and MRI
- VII. **Term and Termination:** The initial term of this Agreement shall be from the 1<sup>st</sup> day of November 2004 and shall continue until the 30<sup>th</sup> day of November 2005 unless otherwise terminated by either party as provided herein. Unless earlier terminated, this Agreement shall continue for successive one year terms. Either party may terminate this Agreement upon 30 days written notice to the other party or may immediately terminate this Agreement upon filing written notice of any material breach of its terms by the other party.

**VIII. Miscellaneous**

**Endorsement of JHUSOM:**

**Authorized Institutional Official**

*Michael J. Klag*  
**Signature:**

**Date:** 10/11/04

**Michael J. Klag, M.D., M.P.H.**

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**Endorsement of NIA IRP:**

**Authorized Institutional Official**

*Dan L. Longo*  
**Signature:**

**Date:** 10/20/04

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